

APR 15 2003

RECEIVED

INFORMATION DISCLOSURE
CITATION

ATTY. DOCKET NO.

1579-527

APPLICANT

HERSHFIELD et al.

FILING DATE

August 23, 2001

SERIAL NO.

09/762,097

GROUP

1652

APR 18 2003

TECH CENTER 1600/2900

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

*EXAMINER INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
<i>CAP</i>	26	3,613,231	10/1974	BERGMEYER et al.	195	66	
<i>CAP</i>	67	4,179,337	12/1979	DAVIS et al.	435	181	
<i>CAP</i>	27	4,460,683	07/1984	GLOGER et al.	435	10	
<i>CAP</i>	28	4,766,106	08/1988	KATRE et al.	514	12	
<i>CAP</i>	29	4,847,325	07/1989	SHADLE et al.	525	54.1	
<i>CAP</i>	30	5,286,637	02/1994	VERONESE et al.	435	183	
<i>CAP</i>	31	5,382,518	01/1995	CAPUT et al.	435	191	
<i>CAP</i>	2	5,428,128	06/1995	MENSI-FATTOHI et al.	530	302	09/27/1994
<i>CAP</i>	32	5,541,098	07/1996	CAPUT et al.	435	191	
<i>CAP</i>	33	5,612,460	03/1997	ZALIPSKY et al.	530	391.9	
<i>CAP</i>	34	5,643,575	07/1997	MARTINEZ et al.	424	194.1	
<i>CAP</i>	35	5,653,974	08/1997	HUNG et al.	424	85.1	
<i>CAP</i>	36	5,880,255	03/1999	DELGADO et al.	530	303	
<i>CAP</i>	3	5,919,455	07/1999	GREENWALD et al.	424	178.1	03/20/1997
<i>CAP</i>	68	6,201,110	03/2001	OLSEN et al.	530	402	
<i>CAP</i>	70	6,245,901	06/2001	VON DER OSTEN	530	402	

FOREIGN PATENT DOCUMENTS

		DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
<i>CAP</i>	37	279 486 A1	06/1990	DD			
<i>CAP</i>	38	279 486 A1	06/1990	DD (Abstract)			
<i>CAP</i>	39	09154581	06/1997	JP			
<i>CAP</i>	40	09154581	06/1997	JP (Abstract)			
<i>CAP</i>	41	WO 94/19007	09/1994	PCT			
<i>CAP</i>	69	WO 00/07629 A2	02/2000	PCT			
<i>CAP</i>	4	WO 01/59078 A2	08/2001	PCT			

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

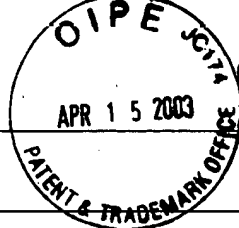
<i>CAP</i>	19	Savoca, K.V., et al., "Induction of Tolerance in Mice by Uricase and Monomethoxypolyethylene Glycol-Modified Uricase," Int. Archs. Allergy Appl. Immunol. 75: 58-67, S. Karger Medical and Scientific Publishers (1984).
<i>CAP</i>	20	Suzuki, H., and Verma, D.P.S., "Soybean Nodule-Specific Uricase (Nodulin-35) Is Expressed and Assembled into a Functional Tetrameric Holoenzyme in Escherichia coli," Plant Physiol. 95: 384-389, American Society of Plant Physiologists (1991).

*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)


**INFORMATION DISCLOSURE
CITATION**

ATTY. DOCKET NO.

SERIAL NO.

1579-527

09/762,097

APPLICANT

HERSHFIELD et al.

(Use several sheets if necessary)

FILING DATE

GROUP

August 23, 2001

1652

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

21	Alvares, K., et al., "Rat urate oxidase produced by recombinant baculovirus expression: Formation of peroxisome crystalloid core-like structures," Proc. Natl. Acad. Sci. USA 89: 4908-4912 (1992).
22	Calicet, P., et al., "Biopharmaceutical Properties of Uricase Conjugated to Neutral and Amphiphilic Polymers," Bioconj. Chem. 10: 638-646 (June 1999).
23	Kelly, S.J., et al., "Diabetes Insipidus in Uricase-Deficient Mice: A model for Evaluating Therapy with Poly (Ethylene Glycol) -Modified Uricase," J. Am. Soc. Nephrol. 12: 1001-1009 (2001).
24	Mountain View Pharmaceuticals, Inc., "PURICASE®," U.S. Trademark Registration Number 2,246,623 (report obtained from U.S. Trademark Electronic Search System (TESS), (April 15, 2003).
25	R&D Focus Drug News (DataStar File IPNR/IPNA), Accession No. 1998:2984 DRUGNL, "PEG-uricase BioTechnology General, Duke University, Mountain View licensing agreement," (August 24, 1998).
42	Abuchowski, A., et al., "Effect of Covalent Attachment of Polyethylene Glycol on Immunogenicity and Circulating Life of Bovine Liver Catalase", Journal of Biological Chemistry 252: 3582-3586 (1977).
43	Burnham, N., "Polymers for Delivering Peptides and Proteins", American Journal of Hospital Pharmacy, 51: 210-218 (1994).
44	Davis, F.F., et al., "Enzyme-Polyethylene Glycol Adducts; Modified Enzymes with Unique Properties", Enzyme Engineering 4: 169-173 (1978).
1	Fuertges, F., et al., "The Clinical Efficacy of Poly(Ethylene Glycol)-Modified Proteins," J. Controlled Release, 11: 139-148 (1990).

*Examiner

Date Considered

Examiner: Initial if reference considered; whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

**INFORMATION DISCLOSURE
CITATION**

ATTY. DOCKET NO.

1579-527

APPLICANT

HERSHFIELD et al.

FILING DATE

August 23, 2001

SERIAL NO.

09/762,097

GROUP

1652

RECEIVED

APR 18 2003

TECH CENTER 1600/2900

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

5	Braun, A., and Alsenz, J., "Development and Use of Enzyme-Linked Immunosorbent Assays (ELISA) for the Detection of Protein Aggregates in Interferon-Alpha (IFN- α) Formulations," Pharm. Res. 14: 1394-1400 (October 1997).
6	Braun, A., et al., "Protein Aggregates Seem to Play a Key Role Among the Parameters Influencing the Antigenicity of Interferon Alpha (IFN- α) in Normal and Transgenic Mice," Pharm. Res. 14: 1472-1478 (October 1997).
7	Colloc'h, N., et al., "Crystal Structure of the protein drug urate oxidase-inhibitor complex at 2.05 Å resolution," Nature Struct. Biol. 4: 947-952 (November 1997).
8	Conley, T.G., and Priest, D.G., "Thermodynamics and Stoichiometry of the Binding of Substrate Analogues to Uricase," Biochem. J. 187: 727-732 (1980).
9	Henney, C.S., and Ellis, E.F., "Antibody Production to Aggregated Human G-Globulin in Acquired Hypogammaglobulinemia," N. Engl. J. Med. 278: 1144-1146 (1968).
10	Kito, M., et al., "A Simple and Efficient Method for Preparation of Monomethoxypolyethylene Glycol Activated with p-Nitrophenylchloroformate and Its Application to Modification of L-Asparaginase," J. Clin. Biochem. Nutr. 21: 101-111 (1996).
11	Kunitani, M., et al., "Classical light scattering quantitation of protein aggregates: off-line spectroscopy versus HPLC detection," J. Pharm. Biomed. Anal. 16: 573-586 (December 1997).
12	Lee, C.C., et al., "Generation of cDNA Probes Directed by Amino Acid Sequence: Cloning of Urate Oxidase," Science 239: 1288-1291 (1988).
13	Mahler, H.R., et al., "Studies on Uricase: I. Preparation, Purification, and Properties of a Cuproprotein," J. Biol. Chem. 216: 625-641 (1955).
14	Montalbini, P., et al., "Uricase from leaves: its purification and characterization from three different higher plants," Planta 202: 277-283 (July 1997).

*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance, and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)


**INFORMATION DISCLOSURE
CITATION**

ATTY. DOCKET NO.

1579-527

APPLICANT

HERSHFIELD et al.

FILING DATE

August 23, 2001

SERIAL NO.

09/762,097

RECEIVED

APR 18 2003

(Use several sheets if necessary)

GROUP

1652

TECH CENTER 1600/2900
U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

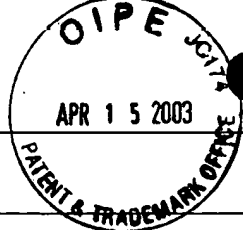
OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

15	Moore, W.V., and Leppert, P., "Role of Aggregated Human Growth Hormone (hGH) in Development of Antibodies to hGH," J. Clin. Endocrinol. Metab. 51: 691-697 (1980).	
16	Osman, A.M., et al., "Liver Uricase in Camelus dromedarius: Purification and Properties," Comp. Biochem. Physiol 94B: 469-474 (1989).	
17	Palleroni, A.V., et al., "Interferon Immunogenicity: Preclinical Evaluation of Interferon- α 2a," J. Interferon Cytokine Res. 17 (Suppl 1): S23-S27 (July 1997).	
18	Porstmann, B., et al., "Comparison of Chromogens for the Determination of Horseradish Peroxidase as a Marker in Enzyme Immunoassay," J. Clin. Chem. Clin. Biochem. 19: 435-439 (1981).	
47	Fam, A.G., "Strategies and Controversies in the Treatment of Gout and Hyperuricaemia," Clinical Rheumatology International Practice and Research 4: 177-192 (1990).	
48	Hande, K.R., et al., "Severe Allupurinol Toxicity," American Journal of Medicine 76: 47-56 (1984).	
49	Hedlund, L.W., et al., "Magnetic Resonance Microscopy of Toxic Renal Injury Induced by Bromoethylamine in Rats," Fundamental and Applied Toxicology 16: 787-797 (1991).	
50	Kahn, K., et al., "Kinetic Mechanism and Cofactor Content of Soybean Root Nodule Urate Oxidase," Biochemistry 36: 4731-4738 (1997).	
51	Kunitani, M., et al., "On-Line Characterization of Polyethylene Glycol-Modified Proteins," Journal of Chromatography 588: 125-137 (1991).	
52	Leach, M., et al., "Efficacy of Urate Oxidase (Uricozyme) in Tumor Lysis Induced Urate Nephropathy," Clinical and Laboratory Haematology 20: 169-172 (1998).	
53	Legoux, R., et al., "Cloning and Expression in Escherichia coli of the Gene Encoding Aspergillus flavus Urate Oxidase," Journal of Biological Chemistry 267: 8565-8570 (1992).	
54	Mahmoud, H.H., et al., "Advances in the Management of Malignancy-Associated Hyperuricaemia," British Journal of Cancer 77 (Supplement 4): 18-20 (1998).	

*Examiner *C. A. Miller* Date Considered *10/10/03*

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)


**INFORMATION DISCLOSURE
CITATION**

ATTY. DOCKET NO.

1579-527

APPLICANT

HERSHFIELD et al.

FILING DATE

August 23, 2001

SERIAL NO.

09/762,097

GROUP

1652

RECEIVED

APR 18 2003

TECH CENTER 1600/2900

(Use several sheets if necessary)

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

55	Nishimura, H., et al., "Improved Modification of Yeast Uricase with Polyethylene Glycol, Accompanied with Nonimmunoreactivity towards Anti-Uricase Serum and High Enzymic Activity," Enzyme 26: 49-53 (1981).
56	Nucci, M.L., et al., "The Therapeutic Value of Poly(Ethylene Glycol)-Modified Proteins," Advanced Drug Delivery Reviews 6: 133-151 (1991).
57	Pui, C.H., et al., "Urate Oxidase in Prevention and Treatment of Hyperuricemia Associated with Lymphoid Malignancies," Leukemia 11: 1813-1816 (1997).
58	Saifer, M., et al., "Plasma Clearance and Immunologic Properties of Long-Acting Superoxide Dismutase Prepared Using 35,000 to 120,000 Dalton Poly-Ethylene Glycol," Advances in Experimental Medicine and Biology 366: 377-387 (1994).
59	Sartore, L., et al., "Enzyme Modification by mPEG with an Amino Acid or Peptide as Spacer Arms," Applied Biochemistry and Biotechnology 27: 45-54 (1991). (55-63)
60	Shearwater Polymers, Inc., "Functionalized Biocompatible Polymers for Research and Pharmaceuticals," Shearwater Polymers, Inc. Catalog, pp. 27, 47 and 48 (1997-1998).
61	Venkataseshan, M.A., et al., "Acute Hyperuricemic Nephropathy and Renal Failure after Transplantation," Nephron 56: 317-321 (1990).
62	Veronese, F.M., et al., "Surface Modification of Proteins," Applied Biochemistry and Biotechnology 11: 141-152 (1985).
63	Veronese, F.M., et al., "New Synthetic Polymers for Enzyme and Liposome Modification" in Poly(ethylene Glycol) Chemistry and Biological Applications, ACS Symposium Series 680, American Chemical Society, Washington, DC, pp. 182-192 (1997).
64	Wu, X., et al., "Hyperuricemia and Urate Nephropathy in Urate Oxidase-Deficient Mice," Proceedings of the National Academy of Sciences USA 91: 742-746 (1994).

*Examiner

Date Considered

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

Form PTO-FB-A820 (Also PTO-1449)

